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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,681	11/08/2001	David G. Barkalow	112703-198	4991

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,681	BARKALOW ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 03/21/05 is acknowledged.

Claims 16-19 and 25-46 are pending. Claims 1-15 and 20-24 have previously been cancelled. Claims 16-19 and 25-46 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/21/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-19, 25-39 and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960).

Meyers teaches an edible film composition and method for making thereof comprising *edible film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, modified starches, dextrin, maltodextrins, gelatin, protein, zein, polyols and combinations thereof including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more *active agents* located in the edible film, which include *dental agents* (*i.e.*, plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors, phosphates, sodium bicarbonate, remineralizing agents); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15- col. 14, line 18); (col. 6, lines 20-44); (col. 7, line 64 – col. 8, line 29); (col. 9, lines 13-34); (col. 10, lines 15-17); (col. 11, lines 49-55) and claims.

Meyers teaches that suitable water-soluble film forming agents include, asides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking

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agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methylcellulose, hydroxypropylcellulose and sodium hydroxymethylcellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The percent ranges of film-forming agents taught by Meyers are overlapping ranges with the instant claims (instant range is ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc, dicalcium phosphate and the like are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (col. 8, line 7 thru col. 10, line 30) (instant range is <20%).

With regard to the instantly claimed 'method of treating halitosis' (claim 19), it is the Examiner's position that since Meyers explicitly teaches active agents comprised of oral dental care agents, such as pH buffers, plaque inhibitors, antimicrobial agents, phosphates, etc., then one of ordinary skill in the art desiring to improve conditions of bad breath or halitosis, would turn to the teachings of Meyers, based on the dental care agents taught therein. The dental agents (*i.e.*, plaque inhibitors, antimicrobials) taught by Meyers would be equivalent and applicable towards the treatment of bad breath or halitosis (see col. 11, lines 49-57).

The film composition of Meyers provides for effective film-forming polymers, bulk fillers, flavoring agents, plasticizers, oral/dental care agents, softeners, emulsifiers and the like.

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It is the position of the Examiner that given the teachings of Meyers, it would be *prima facie* obvious for one of ordinary skill in the art to use the specifically disclosed combination ingredients of Meyers to provide for a film composition that enables delivery of active ingredients, allows for flexibility of the film, as well as breath freshening, germ killing properties, flavor enhancement, etc. The expected result would be an edible film composition that offers maximal and optimal benefits to the consumer.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) as applied to claims 16-19, 25-39 and 41-46 above and further in view of Zerbe *et al.* (US Pat. No. 5,948,430).

Meyers, as discussed above, teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, modified starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches various acids that include for example, stearic, lauric, palmitic, arachidic, oleic, linoleic and eladic acids at column 8, lines 5-11. Meyers does not teach an acid from the instant selective group of claim 40 (citric, lactic, malic, ascorbic, succinic, adipic, fumaric, tartaric acid).

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Zerbe et al. teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids taught include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the particular acids (*i.e.*, tartaric, citric) of the film composition taught by *Zerbe et al.* within the edible film composition of Meyers, because *Zerbe et al.* teach a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (*i.e.*, tartaric, citric) which function to provide an enhancement of flavor to the composition and similarly, Meyers teaches an edible water-soluble film forming composition comprising active agents that include flavor enhancers and acids. The expected result would be an edible film-forming composition that imparts enhancement of flavor, taste and freshness in the mouth of the consumer.

Response to Arguments

Applicant's arguments filed 03/21/05 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 16-19, 25-39 and 41-46 over Meyers (US 5,433,960) stating, "Meyers does not teach or suggest a stand alone edible film composition as recited in the present claims. Rather, Meyers discloses a chewing gum coating that requires a chewing gum piece as a support substrate. All examples in Meyers require a chewing gum stick to support the coating.

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The Meyers coating exhibits adhesive characteristics. Applicant's specification defines a stand alone film as one that does not need structural support ingredients. The art fails to provide a film that does not need structural support ingredients. Thus, Meyers fails to teach a stand alone film composition.

These arguments have been carefully considered but were not found persuasive. Applicant's arguments of a 'stand alone' edible film is not persuasive and it remains the position of the Examiner the "comprising" claim language permits the use of additional ingredients, elements or steps besides from those recited in the instant claims. Additional ingredients, in this instance, could be structural support ingredients, such as those taught by Meyers. The limitation phrase 'stand alone' is not a significant limitation that affects patentability or affords patentable weight. With regard to properties of the film, the prior art teaches properties of increased moisture stability, release of active ingredient, flexibility (from plasticizers/softeners), flavor enhancing and germ-killing (due to antimicrobials) and thus sufficiently provides for all properties desired by Applicant's invention. No unexpected or unusual results have been observed in the components of the instant invention, since the prior art initially clearly recognizes and teaches a similar edible film composition, which comprises the same ingredients for use in the same field of endeavor and to treat the same problems desired by Applicant. Since the prior art teaches the inclusion of the same ingredients for use in the same field of endeavor as Applicants, the results, properties and benefits imparted by those ingredients would also be the same as that claimed by Applicant.

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Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claim 40 over Meyers (US 5,433,960) in view of Zerbe et al. (US 5,948,430) stating, "Zerbe fails to cure the deficiencies of Meyers and therefore the rejection is improper."

Applicants' arguments have been considered but were not persuasive. Meyers, as delineated above teaches an edible film composition and method for making thereof comprising edible film-forming agents, bulk filler agents, plasticizers, active agents that include dental agents, flavor enhancers, sweeteners, softeners and the like. Meyers while teaching flavor acids do not teach the instant selective acids of instant claim 40. Zerbe *et al.* remedies this only deficiency of Meyers by explicitly teaching a film composition comprising acids that include tartaric and citric acid. Ample motivation is provided by the prior art of Zerbe *et al.* since they teach that effect of flavors in the film are enhanced by adding flavor enhancers such as tartaric and citric acids. Similarly Meyers teaches that flavor enhancers, such as acids are also used in his film composition. Therefore, given the teachings of the prior art, the instant invention as a whole would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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May 26, 2005